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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,289	12/12/2003	Jing Zhu	1676.011US1	9939

21186 7590 10/04/2007

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EXAMINER	
HAMUD, FOZIA M	
ART UNIT	**PAPER NUMBER**
1647	

MAIL DATE	DELIVERY MODE
10/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,289	ZHU ET AL.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,24-44 and 47-61* is/are pending in the application.

4a) Of the above claim(s) *47-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21, 24-44, 58-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Applicant's Amendment:

1a. Receipt of Applicants' amendment and arguments, filed on 02 July 2007 is acknowledged.

Status of Claims:

1b. Claims 22-23 have been cancelled, new claims 58-61 have been added. Thus, claims 1-21, 24-44, 47-61 are pending, of which claims 47-57 stand withdrawn for being drawn to non-elected invention. Claims 1-21, 24-44 and 58-61 are under consideration in the instant application.

2. The following rejections are withdrawn in light of Applicant's amendment:

I. The objection that the title of the invention is not descriptive is withdrawn, because Applicants' argument that the title "Use of Proepithelin to Promote Wound Repair and Reduce Inflammation" is descriptive is found persuasive.

II. The objection to the disclosure as containing an embedded hyperlink and/or other form of browser-executable code is withdrawn. Applicants' argument that the specification as filed is fully enabled and that the information provided by the hyperlink is not essential for such enablement and that the hyperlink is to http://www.ncbi.nlm.nih.gov, which is not a commercial website. Instead, it is a govemment (non-commercial) website providing information without any pressing any commercial issues or interests, is found persuasive.

III The rejection of claims 1-46 made under 35 U.S.C. 112, first paragraph, because the specification, for not enabling the scope of the claims is withdrawn, in light of the following rejection.

IV. The objection of claims 3, 4, 6, 26, 27 and 29 for reciting non-elected sequences, is withdrawn, since the claims no longer recite non-elected sequences.

Claim Rejections Under 35 U.S.C. § 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-21, 24-44, 58-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of promoting epithelial proliferation without eliciting production of IL-8, a method of blocking TNF induced neutrophil activation by PEPI, a method of forming a complex between PEPI and SLPI, does not reasonably provide enablement for a method of wound healing in a mammal or inhibiting inflammation in a mammal afflicted with a wound, by administering proepithelin polypeptide (PEPI) alone or in combination with the secretory leukocyte protease inhibitor SLPI. The specification does not enable any person skilled in the art, to which it pertains, or with which it is most nearly connected, to practice the invention.

Claims 1-2 and 24-25 1-21, 24-44, 58-61 encompass a method of enhancing wound healing or a method of inhibiting inflammation in a mammal afflicted with a wound by administering PEPI, alone or in combination with SLPI. However, the instant specification discloses that SLPI and PEPI form complexes, which prevents elastase

from converting proepithelin to epithelins, (see page 2, lines 25-31). The specification further discloses that while epithelins inhibit the growth of epithelial cells and induce the proinflammaotry cytokine IL-8, PEPI promotes epithelial proliferation, blocks TNF induced neutrophil activation and prevents the release of oxidants and proteases, (see pages 2-3). Thus, the specification only discloses that PEPI and SLPI form complexes and that PEPI promotes epithelial proliferation and inhibits TNF induced neutrophil activation.

The instant specification discloses that the retarded healing of SLPI-deficient mice was fully normalized by SLPI, as well as by PEPI (see Example 6 and Figures 7B and 7C). However, it is disclosed that in wild type mice, application of SLPI and PEPI had no effect on the rate of healing (see page 54, lines 12-17). Therefore, since neither PEPI nor SLPI had any effect on the healing rate of wild type mice and since the wild type mice would be more representative of a normal mammal in need of wound healing, (rather than the SLPI mice), the instant specification teaches away from the claimed method. Thus one of ordinary skill in the art would not expect that PEPI alone or PEPI in combination with SLPI, would enhance wound healing or inhibit inflammation in a mammal afflicted with a wound.

The criteria set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those

in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue extermination, in the instant application, the specification teaches that application of SLPI and PEPI had no effect on the rate of healing in wild type mice and that PEPI and SLPI only increased the rate of wound healing in a SLPI deficient mice. However, the claims encompass a method of enhancing wound healing or inhibiting inflammation in a "mammal" afflicted with a wound, the claims do not encompass "an SLPI deficient mammal". Thus, there is no expectation that PEPI alone and SLPI and SLPI would enhance wound healing or inhibit inflammation in a normal mammal.

The Priorart recognizes that SLPI plays a role in inflammation. For example, U.S. Patent 5,290,762, (Lezdey et al, 01 March 1994) disclose a method for the treatment of inflammatory diseases or injury in mammals by administering to the site of the disease or injury an effective amount of secretory leucocyte protease inhibitor, (see claims). Also Jin et al teach that SLPI inhibits the inflammatory responses of macrophages and monocytes to microbial products (Jin et al., 1998, cited on the IDS of 11 march 2004). However, the prior art is silent on the effect of PEPI on wound healing or inflammation. Thus, since the instant specification teaches that SLPI and PEPI had no effect on wound healing or inhibiting inflammation on a wild type mammal, the specification is not enabling for the claimed method. The specification is only enabling for a method of promoting epithelial proliferation without eliciting production of IL-8, a method of blocking TNF induced neutrophil activation by PEPI, or a method of forming a complex between PEPI and SLPI.

Claim Rejections - 35 USC § 112, second paragraph:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 17, 18, 40, 41, 59 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4a. Claims 4, 27 recite the article "an" when referring to a specific protein, however, this renders the claim vague and indefinite, because unclear whether only part of the polypeptide of SEQ ID NO:7 is being referred to. It is suggested that the claims be amended to recite the article "***the",*** when referring to a specific sequence, for example ".....comprises the amino acid sequence of SEQ ID NO:7....". Appropriate correction is required.

4b. Claims 17 and 18, recite "the method of *claims* 1....", however, since the claims depend only from one claim, they should recite "claim 1".

4c. Claims 18 and 59 should depend from claim 2, because claim 2, not claim 1 recites "seretory leukocyte protesase inhibitor".

4c. Claims 40 and 41, recite "the method of *claims* 24....", however, since the claims depend only from one claim, they should recite "claim 24".

4d. Claims 41 and 61 should depend from claim 25, since it is claim 25, recites "secretory leukocyte protease inhibitor".

Conclusion:

5. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisory Manjuanth N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
07 September 2007

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER